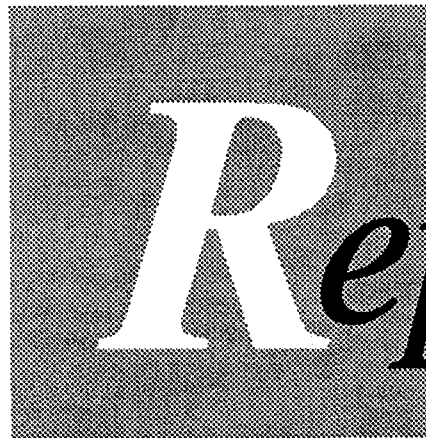




Audit



Report

YEAR 2000 COMPLIANCE STATUS OF BIOMEDICAL DEVICES
INCLUDED IN NAVY FLEET HOSPITALS

Report No. D-2000-048

December 3, 1999

Office of the Inspector General
Department of Defense

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Acronyms

EKG	Monitor-Recorder Electrocardiograph
FDA	Food and Drug Administration
FH	Fleet Hospital
FHPO	Fleet Hospital Program Office
Y2K	Year 2000



INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202

December 3, 1999

MEMORANDUM FOR NAVAL INSPECTOR GENERAL

SUBJECT: Audit Report on Year 2000 Compliance Status of Biomedical Devices
Included in Navy Fleet Hospitals (Report No. D-2000-048)

We are providing this report for information and use. This report is one in a series on Deployable Medical Systems Operations, Navy Fleet Hospital Program. This report specifically addresses the year 2000 compliance status of biomedical devices included in Navy fleet hospitals. The report is also one in a series of reports being issued by the Inspector General, DoD, in accordance with an informal partnership with the Chief Information Officer, DoD, to identify progress made by DoD Components who are preparing information and technology systems for year 2000 compliance.

Comments from the Office of the Chief, Bureau of Medicine and Surgery, on a draft of this report were considered in preparing the final report. The Navy concurred with the recommendations and the comments conformed to the requirements of DoD Directive 7650.3; therefore, no additional comments are required. We commend the proactive approach taken by the Navy in resolving the issues identified in the report.

We appreciate the courtesies extended to the audit staff. Questions on the audit should be addressed to Mr. Michael A. Joseph at (757) 766-9108 (mjoseph@dodig.osd.mil) or Mr. Michael F. Yourey at (757) 766-3268 (myourey@dodig.osd.mil). See Appendix C for the report distribution. The audit team members are listed inside the back cover.

A handwritten signature in black ink, reading "Robert J. Lieberman", is positioned above the printed name.

Robert J. Lieberman
Assistant Inspector General
for Auditing

Office of the Inspector General, DoD

Report No. D-2000-048

(Project No 9LF-0093)

December 3, 1999

Year 2000 Compliance Status of Biomedical Devices Included in Navy Fleet Hospitals

Executive Summary

Introduction. This report is one of a series being issued by the Inspector General, DoD, in accordance with an informal partnership with the Chief Information Officer, DoD, to monitor DoD efforts to address the year 2000 computing challenge. For a complete listing of audit projects addressing the issue, see the year 2000 web pages on the IGnet at <http://www.ignet.gov>.

The Navy maintains 10 500-bed fleet hospitals in its Deployable Medical Systems inventory. Eight of the hospitals are pre-positioned throughout the world. The fleet hospitals are containerized and are equipped with biomedical devices such as anesthesia apparatus, monitor-recorder electrocardiographs, and visual ultrasonic apparatus. Each fleet hospital requires about 450 containers for storage. The Navy Fleet Hospital Program Office was a detachment of the Naval Supply Systems Command until October 1, 1999. On October 1, 1999, the office was realigned under the Navy Bureau of Medicine and Surgery.

Objectives. This report is the first in a series on Deployable Medical Systems Operations, Navy Fleet Hospital Program. The overall audit objective was to determine whether the Navy Fleet Hospital Program is based on requirements necessary to support DoD operations plans. This report specifically addresses the year 2000 compliance status of biomedical devices included in Navy fleet hospitals.

Results. The Navy Fleet Hospital Program Office incorrectly certified that none of its biomedical devices included in Navy fleet hospitals would experience year 2000-related performance problems. The Fleet Hospital Program Office did not document its certification process and did not include items to be deleted from the fleet hospital inventory in its certification. The Navy Fleet Hospital Program Office also did not report its certification to higher Navy management. As a result, fleet hospitals could be deployed with year 2000 noncompliant biomedical devices. During the audit, the Fleet Hospital Program Office initiated actions to reevaluate fleet hospital biomedical devices for compliance and to plan workarounds for year 2000 noncompliant biomedical devices that will remain in the fleet hospitals after December 31, 1999. For details of the audit results, see the Finding section.

Summary of Recommendations. We recommend that the Chief, Bureau of Medicine and Surgery, assess the feasibility of the workarounds and ensure procedures are in place to effectively implement the workarounds.

Management Comments. The Office of the Chief, Bureau of Medicine and Surgery concurred with the finding and recommendations. The Office of the Chief, Bureau of Medicine and Surgery, stated the planned workarounds are adequate and that upon activation, each fleet hospital commanding officer will receive a letter with details about all year 2000 noncompliant biomedical equipment. See the Finding section for a discussion of management comments and the Management Comments section for the complete text of the management comments.

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Background

Executive Order 13073. Because there is a potential for computers to fail to run or function throughout the Government on January 1, 2000, the President issued Executive Order 13073, "Year 2000 Conversion," February 4, 1998. The Executive Order makes it policy that Federal agencies ensure that no critical Federal program experiences disruption because of the year 2000 (Y2K) problem. The order requires that the head of each agency ensure that efforts to address the Y2K problem receive the highest priority attention in the agency. The order also listed health care as one of five critical areas in which the Federal Government should cooperate with the private sector.

DoD Y2K Management Strategy. In his role as the DoD Chief Information Officer, the Assistant Secretary of Defense (Command, Control, Communications, and Intelligence) issued version 1.0 of the "DoD Year 2000 Management Plan" (the DoD Management Plan) in April 1997. The DoD Management Plan is a living document and has had numerous revisions. Version 1.0 required DoD Components to implement a five-phase (awareness, assessment, renovation, validation, and implementation) Y2K management process. However, a later version reduced the five-phase management process to three phases (inventory, assessment, and implementation) for biomedical devices, facility devices, and other embedded chip applications. The DoD Management Plan makes DoD Components responsible for implementing the Y2K management process.

Year 2000 Responsibilities for Health Care Systems. Y2K issues in DoD health care primarily encompass automated information systems, biomedical devices, and facility devices. The Assistant Secretary of Defense (Health Affairs) is responsible for providing oversight of Y2K compliance for biomedical devices. The Assistant Secretary of Defense (Health Affairs) reports quarterly the Y2K status of biomedical devices to the Assistant Secretary of Defense (Command, Control, Communications, and Intelligence) and the Office of Management and Budget. Each Military Department is responsible for correcting potential Y2K problems in biomedical devices.

Navy Y2K Action Plan. The "Bureau of Medicine and Surgery Management Plan for Medical Devices," (the Navy Management Plan), September 1998, defines roles, responsibilities, and reporting requirements and lays a foundation to ensure no failure occurs because of Y2K-related problems. The plan provides guidance to ensure that no patients or staff are adversely affected by the effect of the year 2000 on medical devices. As part of the Navy Management Plan, the Naval Medical Logistics Command developed a plan providing Navy-wide guidance for identifying and implementing corrective action for noncompliant biomedical devices. It also developed a list of "Medical Device Risk Levels for Year 2000 Compliance Evaluation" (the Y2K Compliance Evaluation List) of all medical devices that potentially could harm patients if the device failed because of Y2K problems. The Navy delegated responsibility for reporting compliant and noncompliant equipment to major commands. The Naval Medical Logistics Command coordinated the

Y2K review of biomedical devices at all Navy medical treatment facilities and was responsible for reporting results to the Office of the Surgeon General of the Navy. Because the biomedical devices included in Navy fleet hospitals (FHs) were the responsibility of the Naval Supply Systems Command rather than a military treatment facility, the Naval Medical Logistics Command did not assess or report on those devices.

Fleet Hospital Organizational Alignment. The Fleet Hospital Program Office (FHPO), located at Fort Detrick, Maryland, reported to the Commander, Naval Supply Systems Command. The FHPO provides overall program management to the fleet hospitals. The FH Support Office, Cheatham Annex, Virginia, manages the inventory. Funding for the program rests with the Director, Naval Medicine, in the Office of the Chief of Naval Operations. Effective October 1, 1999, the FH program management and operations transferred to the Navy Bureau of Medicine and Surgery.

Fleet Hospital Concept. The Navy maintains readiness for 10 FHs by servicing 2 hospitals a year. The remaining eight FHs are pre-positioned throughout the world. The FHs are containerized deployable medical systems that are assembled into 500-bed hospitals. The FHs include biomedical devices such as anesthesia apparatus, monitor-recorder electrocardiographs (EKGs), and visual ultrasonic apparatus. Each FH requires about 450 storage containers. The FHs are designed to treat casualties of dual major theater wars.

Each FH is scheduled for repair and maintenance every 5 years. The FH Support Office uses "build-to" and "as-built" reports to accomplish its repair and maintenance of the FHs. The build-to report shows the equipment and supplies currently approved for use in the FHs. The as-built report shows actual equipment and supplies in each FH. Although items on the as-built report are stored in the FH, some items may not be approved by the current build-to report. As items on the as-built report become outdated or are no longer required, they are removed from the build-to report. However, such items remain in the FH until it is brought to Cheatham Annex for repair and maintenance. For purposes of this report, the outdated and no-longer-required items are referred to as "deleted" items.

Objectives

This is the first in a series of reports on Deployable Medical Systems Operations, Navy Fleet Hospital Program. The overall audit objective was to determine whether the Navy Fleet Hospital Program is based on requirements necessary to support the DoD operations plans. This report addresses the Y2K compliance status of biomedical devices included in Navy FHs. See Appendix A for a discussion of the audit scope and methodology and Appendix B for a summary of prior coverage.

Year 2000 Status of Biomedical Devices Included in Navy Fleet Hospitals

The FHPO incorrectly certified that none of its biomedical devices included in FHs would experience Y2K-related performance problems. The FHPO did not document its certification process and did not include deleted items in its evaluation. It also failed to report its certification to higher Navy management. As a result, FHs could be deployed with Y2K noncompliant biomedical devices. During the audit, the FHPO initiated actions to reassess the Y2K compliance of biomedical devices included in FHs and to plan workarounds for Y2K noncompliant biomedical devices that will remain in the FHs after December 31, 1999.

Year 2000 Compliance

Certification of FH Devices. On March 9, 1999, the FHPO incorrectly certified that none of the FH biomedical devices would experience Y2K-related performance problems. The March 9, 1999, certification consisted of an internal memorandum addressed to the Program Manager, FHPO, attaching a 12-page equipment list. The memorandum stated the equipment list was reconciled against a medical equipment database identifying equipment with known Y2K discrepancies.

The certification process began November 24, 1998, when FHPO instructed its inventory manager, the FH Support Office, to provide a list of biomedical devices included in the FHs by December 16, 1998. The FH Support Office submitted a list of biomedical devices to FHPO for verification against the Y2K Compliance Evaluation List.

Adequacy of Documentation Supporting the Certification. The FHPO was unable to provide any documentation supporting its certification of the FH biomedical devices. The Navy Management Plan states documentation for Y2K compliance will be designed so that all applicable Y2K information for biomedical equipment will be readily accessible, well organized, and easily maintained.

Deleted Items. The FHPO did not include deleted items in its certification process. We judgmentally sampled 32 of 289 items from the August 3, 1999, FH Support Office consolidation of the build-to and as-built reports that were also on the Y2K Compliance Evaluation List or the Food and Drug Administration's "Computer-Controlled Potentially High Risk Medical Devices-List of Device Types," (FDA List). Two EKGs included in the FHPO certification were shown as Y2K noncompliant on the manufacturer's web page. There were 589 of the EKGs included in the 10 FHs. The EKGs were deleted items and had not been considered when the FHPO did its Y2K compliance certification. After further research, we found that the FHPO had excluded all deleted items from the certification.

Reporting Requirement. As of August 24, 1999, the FHPO had not reported its Y2K certification to the Naval Supply Systems Command although required to do so by the Navy Management Plan. According to the Navy Management Plan, reporting was an integral part of the Y2K certification, and impacted the Navy-wide success or failure of its Y2K compliance process. In addition, because the devices were not reported through the Navy chain of command, they were also omitted from any reports to the Office of the Assistant Secretary of Defense (Command, Control, Communications, and Intelligence) and the Office of Management and Budget.

Management Actions During the Audit

Throughout the audit, we worked closely with the FHPO staff. As we identified problems, we notified FHPO staff members and they initiated corrective actions. During the audit, we provided the FHPO with a listing of compliant biomedical devices obtained from the Joint Readiness Clinical Advisory Board to assist in completing its Y2K certification of the biomedical devices.

From August 24 through August 31, 1999, the FHPO reassessed the biomedical devices included in all FHs for Y2K compliance. On August 31, 1999, the FHPO forwarded its report of reassessment to the Y2K Coordinator, Naval Medical Logistics Command. The FHPO also forwarded an information copy of the report to the Naval Supply Systems Command. The FHPO reported all medical devices within the FH program were researched and found to fall under the compliant or "compliant with workaround" classification. Two devices, the EKGs identified by the audit, and some defibrillators, required workarounds. For example, according to Hewlett Packard, the manufacturer of the EKGs, the date and time will not print on the recording strip or show on the monitor display. Hewlett Packard recommended that corrective action be performed by Hewlett Packard-qualified personnel or that the customer set the year to a different date than 1999. The workarounds were approved by the Naval Medical Logistics Command.

Workarounds are viable solutions for some biomedical devices. However, because of the length of time that the devices might remain in the FHs, we believe the Bureau of Medicine and Surgery should assess the feasibility of such workarounds for use in FHs and ensure that procedures are in place to effectively implement the workarounds. If FHs are deployed, Navy medical or technical personnel will be expected to reset the time and date functions on deleted EKGs. Not only will the personnel have to know they must reset the time and date on the EKGs, they must know which EKGs require the workaround. Documented workaround procedures are critical because, as discussed previously, the items might remain in the FHs for several years before the workaround will be implemented.

Recommendations and Management Comments

We recommend that the Chief, Bureau of Medicine and Surgery:

1. Assess the feasibility of workarounds planned by the Fleet Hospital Program Office, considering the length of time such “compliant with workaround” devices will remain in the fleet hospitals.

Management Comments. The Office of the Chief, Bureau of Medicine and Surgery, concurred and forwarded a Naval Medical Logistics Command memorandum stating the planned workarounds are adequate for the safe and effective operation of pre-positioned medical equipment.

2. Ensure procedures are in place to effectively implement workarounds determined to be feasible.

Management Comments. The Office of the Chief, Bureau of Medicine and Surgery, concurred, stating that upon activation, each fleet hospital commanding officer will receive a letter detailing all Y2K noncompliant biomedical equipment. The letter will also provide the workarounds or list the replacement equipment included in the fleet hospital follow-on package.

Appendix A. Audit Process

This is one in a series of reports being issued by the Inspector General, DoD, in accordance with an informal partnership with the Chief Information Officer, DoD, to monitor DoD efforts to address the Y2K computing challenge. For a list of audit projects addressing the issue, see the Y2K web pages on IGnet at <http://www.ignet.gov>.

Scope and Methodology

As part of our audit of Deployable Medical Systems Operations, Navy Fleet Hospital Program, we looked at the Y2K status of biomedical devices included in Navy FHs, focusing on the Y2K compliance certification of biomedical devices completed by the FHPO. We reviewed the March 9, 1999, FHPO memorandum certifying that none of its biomedical devices included in FHs would experience Y2K-related performance problems; FH Support Office memorandums dated November 30, 1998, through August 2, 1999, identifying Y2K compliance issues; and the FH Support Office build-to and as-built reports of Y2K compliant biomedical devices contained in the FHs. We evaluated the methods that the FHPO used to certify the Y2K compliance of the biomedical devices contained in the FHs and met with cognizant Navy program officials to discuss the Y2K certification process.

We selected a judgmental sample to verify the accuracy of FHPO Y2K compliance certification. The sample consisted of 32 biomedical devices selected from the August 3, 1999, FH Support Office consolidation of the build-to and as-built reports. The 32 devices selected were included on the FDA List, June 29, 1999, or the Y2K Compliance Evaluation List, July 7, 1999. The Y2K Compliance Evaluation List identified 15 items as high risk and 17 as medium risk. We verified Y2K compliance by researching the FDA and National Institutes of Health web site databases and manufacturer web sites. We contacted the manufacturer when we needed additional information. We found that 2 of the 32 items were Y2K noncompliant. The noncompliant items were deleted items no longer on the approved build-to report. Further research showed that the FHPO had excluded all deleted items from its Y2K compliance certification.

DoD-Wide Corporate-Level Goals. In response to the Government Performance and Results Act, DoD has established 2 DoD-wide goals and 7 subordinate performance goals. This report pertains to achievement of the following goal (and subordinate performance goal).

Goal 2: Prepare now for an uncertain future by pursuing a focused modernization effort that maintains U.S. qualitative superiority in key warfighting capabilities. Transform the force by exploiting the

Revolution in Military Affairs, and reengineer the Department to achieve a 21st century infrastructure. **Performance Goal 2.2:** Transform U.S. military forces for the future. (00-DoD-2.2)

DoD Functional Area Reform Goals. Most major DoD functional areas have also established performance improvement reform objectives and goals. This report pertains to achievement of the following functional area objective and goal.

Health Care Functional Area. Objective: Ensure joint medical readiness capabilities. **Goal:** Ensure doctrinally sound, operationally integrated, joint medical force capable of successfully meeting health service demands throughout the continuum of military operations. (MHS-1.2)

High-Risk Area. In its identification of risk areas, the General Accounting Office has specifically designated risk in resolution of the Y2K problem as high. This report provides coverage of that problem.

Audit Type, Dates, and Standards. We performed this program audit from August through September 1999 in accordance with auditing standards issued by the Comptroller General of the United States, as implemented by the Inspector General, DoD. We did not rely on computer-processed data to perform the audit.

Contacts During the Audit. We visited or contacted individuals and organizations within DoD and manufacturers of selected biomedical devices. Further details are available upon request.

Management Control Program. We did not review the management control program related to the overall audit objective because DoD recognized the Y2K issue as a material management control weakness area in the FY 1998 Annual Statement of Assurance.

Appendix B. Summary of Prior Coverage

The General Accounting Office and the Inspector General, DoD, have conducted multiple reviews related to Y2K issues. General Accounting Office reports can be accessed over the Internet at <http://www.gao.gov>. Inspector General, DoD, reports can be accessed over the Internet at <http://www.dodig.osd.mil>. The Inspector General, DoD, has issued six final audit reports discussing Y2K issues in DoD health care.

Inspector General

Inspector General, DoD, Report No. D-2000-046, "Year 2000 Computing Issues Related to Health Care in DoD – Phase III," December 1, 1999.

Inspector General, DoD, Report No. D-2000-042, "Year 2000 Operational Contingency Planning for Health Care in the European Theater," November 26, 1999.

Inspector General, DoD, Report No. D-2000-031, "Year 2000 End-to-End Tests for the Military Health System," November 4, 1999.

Inspector General, DoD, Report No. 99-255, "Year 2000-Sensitive Property Reutilized, Transferred, Donated, or Sold," September 15, 1999.

Inspector General, DoD, Report No. 99-196, "Year 2000 Computing Issues Related to Health Care in DoD – Phase II," June 29, 1999.

Inspector General, DoD, Report No. 99-055, "Year 2000 Computing Issues Related to Health Care in DoD," December 15, 1998.

Appendix C. Report Distribution

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Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
Senate Special Committee on the Year 2000 Technology Problem
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services

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House Subcommittee on Government Management, Information, and Technology,
Committee on Government Reform

House Subcommittee on National Security, Veterans Affairs, and International
Relations, Committee on Government Reform

House Subcommittee on Technology, Committee on Science

Chief, Bureau of Medicine and Surgery Comments



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

6700
Ser 09C/008
23 Nov 99

From: Chief Bureau of Medicine and Surgery (MED-09C)
To: Department of Defense, Office of the Inspector General

Subj: DRAFT AUDIT REPORT ON YEAR 2000 COMPLIANCE REPORT OF
BIOMEDICAL DEVICES INCLUDED IN NAVY FLEET HSOPITALS
(PROJECT NO. 9LF-0093)

(a) IG DoD memo of 21 Oct 99

(1 MEDLOGCOM ltr 6700 Ser 00/024-99 of 04 Nov 99

1. In response to reference (a), BUMED forwards enclosure (1 concurring with the findings and recommendations.

2. As clarification of the "Commanding Officer's Letter of Direction" contained in paragraph 2, each commanding officer of the activated fleet hospital will receive a letter detailing all non Y2K complaint biomedical equipment. Further, the letter will provide the work around for the devices or list of the replacement equipment included in the fleet hospital's "fly-in" package.

3. If there are any further questions. Please do not hesitate contacting me at (202) 762-3269.

A handwritten signature in black ink, appearing to read "R. C. Foster", is positioned above the typed name.

R. C. FOSTER
By direction

Copy to:
MEDLOGCOM



DEPARTMENT OF THE NAVY

NAVAL MEDICAL LOGISTICS COMMAND
FORT DETRICK, MARYLAND 21702-5015

6700 IN REPLY REFER TO
Ser 00/024-99
04 Nov 99

From Commanding Officer, Naval Medical Logistics Command
To: Chief, Bureau of Medicine and Surgery (MED-09C)


Subj: DRAFT AUDIT REPORT ON YEAR 2000 COMPLIANCE STATUS OF
BIOMEDICAL DEVICES INCLUDED IN NAVY FLEET HOSPITALS
(PROJECT NO. 9LF-0093)

Ref: (a) IG DOD memo of 21 Oct 99

1. Reference (a) requested comments on subject report regarding Year 2000 compliance status of biomedical devices included in Navy Fleet Hospitals.

2. NMLC concurs with the findings and recommendations of reference (a). The workarounds planned by this office are adequate for the safe and effective operation of prepositioned medical equipment. All pieces of equipment will be certified to be compliant when the prepositioned equipment is checked during its scheduled service life extension program (SLEP). Until that time, the workaround procedures will be included in the Commanding Officer's Letter of Direction upon activation of the individual units.

3. The Fleet Hospital Program is Year 2000 compliant or has compliant workaround for all biomedical devices.


T. R. DEFIBAUGH

Audit Team Members

The Readiness and Logistics Support Directorate, Office of the Assistant Inspector General for Auditing, DoD, prepared this report. Personnel from the Office of the Inspector General, DoD, who contributed to the report are listed below.

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